REMARKS

This is a full and timely response to the non-final Official Action mailed **July 1, 2008**. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Claims 22-53 and 63-79 were withdrawn from consideration under the imposition of a previous Restriction Requirement and cancelled without prejudice or disclaimer. Subsequently, claims 2, 6, 55, 59, 61 and 99 were also cancelled without prejudice or disclaimer

No further changes to the claims are proposed by the present paper. Thus, claims 1, 3-5, 7-21, 54, 56-58, 60, 62 and 80-98 are currently pending for further action.

Prior Art:

Claims 1, 5-14, 21, 54, 57, 58, 60, 80, 86, 88, 89, 91, 94, 96, 97 and 99 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of U.S. Patent App. Pub. No. 2003/0059471 to Compton et al. ("Compton") and U.S. Patent App. Pub. No. 2002/0197388 to Brown et al. ("Brown"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

> A method for producing an oral medication comprising:
> with an inkjet dispenser, dispensing a structural material, said structural material including one of a polymer or a gelatin;
> curing said structural material;
> with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material; and

d*ispensing alternating layers of said structural material and said pharmaceutical solution.*
(Emphasis added).

In contrast, Compton teaches a composition that includes "a plurality of discrete, substantially flat flakes…wherein the flakes comprise a drug or a nondrug nonnutritional active agent." (Compton, paragraph 0012). Compton further teaches that "in some cases, inert materials (e.g. gels, absorbents, etc.) may be used to create a flake" wherein the fabrication process includes "[i]nkjet[ting]…slurry onto belt dryer or barrel or flat surface drying device," drying the slurry by heat or vacuum, and/or polymerizing the flakes by radiation. (Id., paragraphs 0331 to 0335). Compton further teaches that "[t]he flake may then be placed in contact with a drug so that [the drug] is absorbed. A subsequent drying or other step (e.g. polymerization) may be necessary to complete the formation of the flake." (Id.).

As has been conceded by the Examiner, "Compton et al. fails to teach using the same inkjet used to dispense the structural material [and] to dispense the pharmaceutical solution as required by claim 1." (Action, p. 3). As a result, the recent Office Action attempts to demonstrate *prima facie* obviousness by citing to Brown's teaching that an "an ink jet head is used to apply [active] coating material to the substrate." (Id., Brown, paragraphs 0040-0041). However, Brown does not teach or suggest here or elsewhere the concept of using the same inkjet dispenser to dispense both "a structural material" and "a jettable pharmaceutical solution onto said cured structural material" as recited by claim 1.

By using the same inkjet dispenser to dispense both structural material and the pharmaceuticals solution onto the structural material, the efficiency of the claimed step of "dispensing alternating layers of said structural material and said pharmaceutical solution" is increased. Thus, dispensing the structural material and the jettable pharmaceutical solution using the same inkjet dispenser provides a significant advantage that cannot be ignored.

Moreover, both Compton and Brown utterly fail to teach or suggest the claimed step of "dispensing alternating layers of said structural material and said pharmaceutical solution." (claim 1). Nevertheless, the recent Office Action erroneously asserts that Compton teaches this subject matter by citing to Compton's teaching that "[t]he flakes also can be formed of a variety of layers, some of which can act as a coating...Such layered flakes can be manufactured easily, such as, for example, by pressing two or more layers together, by spraying a plurality of layers sequentially on a belt or drum, by vortexing preformed flakes to render them airborne in a mist that will coat the flakes to create another layer, and so on." (Compton, paragraph 0044). Nowhere in the cited portions of Compton or elsewhere does Compton teach or suggest using a single inkjet dispenser to dispense "alternating layers of said structural material and said pharmaceutical solution." (Claim 1).

Under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966) to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Compton and Brown, did not include the claimed subject matter, particularly the steps of "with *said inkjet dispenser*, dispensing a jettable pharmaceutical solution onto said cured structural material" and "dispensing alternating layer of said structural material and said pharmaceutical solution." (Claim 1, emphasis added).

The differences between the cited prior art and the claimed subject matter are significant because the claimed subject matter "produce[s] a layered solid oral dosage form of a pharmaceutical without the traditionally complex and costly manufacturing process" and is "precisely formed using inkjet technology." (Applicant's specification, paragraph 0025). Thus, the claimed subject matter provides feature and advantages not known or available in

the cited prior art. Consequently, the cited prior art will not support a rejection of claim 1 under 35 U.S.C. § 103 and *Graham*. For at least these reasons, the rejection of claim 1 and its corresponding dependent claims should be reconsidered and withdrawn.

Claim 54 recites:

> A method for forming a slow release dosage of oral medication comprising:
> disposing a first layer of polymer based structural material adjacent to an inkjet dispenser;
> jetting a jettable pharmaceutical solution onto said polymer based structural material with said inkjet dispenser, wherein said solution comprises a solvent for dissolving said solution into said structural material; and
> depositing a second layer of polymer based structural material over said pharmaceutical solution; and *varying a quantity of said first and second layer of polymer based structural material to vary a release rate of said pharmaceutical solution*.

(Emphasis added).

In contrast, neither Compton nor Brown teaches or suggests the subject matter of claim 54. Specifically, both Compton and Brown completely fail to teach or suggest the claimed step of "varying a quantity of said first and second layer of polymer based structural material to vary a release rate of said pharmaceutical solution." (Claim 54). The recent Office Action fails to acknowledge or address this recitation in claim 54, and therefore cites no portion of Compton or Brown that allegedly teaches or suggests this subject matter.

According to the Supreme Court, the Examiner is required to provide an explicit analysis as to how the cited prior art teaches or suggests all the features of a claim. "To facilitate review, this [the Examiner's] analysis should be made explicit." (*KSR International Co. v. Teleflex, Inc.*, 550 U.S. ___ (2007). Therefore, under the standard of *KSR*, no *prima facie* case of obviousness has been made as to claim 54. For at least this reason, the rejection of claim 54 should be withdrawn.

Moreover, under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966) to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Compton and Brown, did not include the claimed subject matter, particularly the step of "varying a quantity of said first and second layer of polymer based structural material to vary a release rate of said pharmaceutical solution." (Claim 54).

The differences between the cited prior art and the claimed subject matter are significant because the claimed subject matter "produce[s] a layered solid oral dosage form of a pharmaceutical without the traditionally complex and costly manufacturing process" and is "precisely formed using inkjet technology." (Applicant's specification, paragraph 0025). Thus, the claimed subject matter provides feature and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 54 under 35 U.S.C. § 103 and *Graham*. For at least these reasons, the rejection of claim 54 and its corresponding dependent claims should be reconsidered and withdrawn.

Dependent claims 15-20, 60, 62 and 83 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton, Brown and U.S. Patent No. 6,602,511 to Von Corswant ("Corswant"). This rejection respectfully traversed for at least the same reasons given above in favor of the patentability of independent claims 1 and 54.

Dependent claims 3-4 and 56 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton, Brown, and U.S. Patent App. Pub. No. 2003/0065294 to Lo et al. ("Lo"). This rejection is respectfully traversed for at least the same reasons given above in favor of the patentability of independent claims 1 and 54.

Dependent claims 81-82 and 92-93 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton, Brown, Corswant and a European patent document having publication number DD 217989 to Bombor et al. ("Bombor"). This rejection is respectfully traversed for at least the same reasons given above in favor of the patentability of independent claims 1 and 54.

Additionally, various dependent claims of the application recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 7 recites "curing said alternating layers of said structural material prior to dispensing said alternating layers of said pharmaceutical solution." Both Compton and Brown fail to teach or suggest this subject matter. For at least this additional reason, the rejection of claim 7 should be reconsidered and withdrawn.

Claim 9 recites "dispensing a plurality of selective quantities of said structural material onto discrete locations of a substrate." In response, the Office Action again cites to Compton's teaching that a step in a fabrication method may be to "[i]nkjet, spray, or drip drug slurry onto belt dryer or barrel or flat surface drying device." (Compton, paragraph 0331). Nowhere does Compton or Brown teach or suggest that "a plurality of selective quantities of said structural material" may be dispensed. For at least this additional reason, the rejection of claim 9 should be reconsidered and withdrawn.

Claim 94 recites "depositing a first layer of structural material onto a non-adhesive substrate." The recent Action asserts that "Compton et al. does not state that the belt is made of an adhesive material therefore the belt is non adhesive and furthermore in the process and the intended product one of ordinary skill would not use an adhesive surface which would affect the releasability of the oral medication from the belt." (Action, p. 5). Applicant wishes

to remind the Examiner that the teachings of Compton must be taken on the merits of what Compton discloses alone, and not inferences made by the Examiner based on what Compton fails to teach. As such, Applicant expressly refuses to accept or acquiesce to the Examiner's flawed reasoning here, and requests that the Examiner provide evidence to back up this assertion.

Claim 95 recites "wherein said non-adhesive substrate comprises glass or polytetrafluorethylene." Neither Compton nor Brown appear to teach or suggest this subject matter, and the recent Office Action completely fails to address this claim. For at least this additional reason, the rejection of claim 95 should be reconsidered and withdrawn.

Conclusion:

In view of the following arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicants reserve the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: October 1, 2008

/Steven L. Nichols/
Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095
(801) 572-8066
(801) 572-7666 (fax)